This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

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PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY PACKAGE INSERT TEMPLATE

Draft Document

Office of Device Evaluation
Division of Cardiovascular, Respiratory and Neurological Devices
Interventional Cardiology Devices Group

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Devices and Radiological Health

PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY PACKAGE INSERT TEMPLATE

PREPARED BY:

INTERVENTIONAL CARDIOLOGY DEVICES GROUP

DIVISION OF CARDIOVASCULAR, RESPIRATORY AND NEUROLOGICAL DEVICES

OFFICE OF DEVICE EVALUATION

FEBRUARY 7, 1995

Percutaneous Transluminal Coronary Angioplasty
Package Insert Template

February 7, 1995

NOTE: This template was sent to all manufacturers of percutaneous transluminal coronary angioplasty (PTCA) dilatation catheters in a letter issued on February 7, 1995. Information presented in ***bold print*** *is required to be present verbatim in all PTCA package inserts. Information not bolded can be tailored for specific catheters.*

I. **Device name** - Brand name and generic name of device

II. **Description** - A description of the catheter with the important components and their function identified.

III. **Indications - The** [device name] **is indicated for balloon dilatation of a hemodynamically significant coronary artery or bypass graft stenosis in patients evidencing coronary ischemia for the purpose of improving myocardial perfusion.**

IV. **Contraindications**

- Unprotected left main coronary artery
- Coronary artery spasm in the absence of a structurally significant stenosis thought to be of hemodynamic significance

V. **Warnings**

- **This device is designed and intended for one time use only. DO NOT resterilize and/or reuse it.**
- **Prior to angioplasty, the catheter should be examined to verify functionality and ensure that its size and shape are suitable for the specific procedure for which it is to be used.**
- **The inflated diameter of the balloon should approximate the diameter of the coronary artery just proximal and distal to the stenosis. The danger of coronary dissection is increased with increasing balloon size: artery ratios above 1:1.**

- **The catheter system should be used only by physicians thoroughly trained in the performance of percutaneous transluminal coronary angioplasty.**

- **When the catheter is in the body, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If strong resistance is met during manipulation, discontinue the procedure and determine the cause of the resistance before proceeding.**

- **Balloon pressure should not exceed the rated burst pressure. Use of a pressure monitoring device is recommended to prevent over-pressurization.**

- **PTCA should only be performed at hospitals where emergency coronary artery bypass graft surgery can be immediately performed in the event of a potentially injurious or life-threatening complication. A cardiac surgery team must be on alert when a PTCA procedure is being performed.**

- **Use only the appropriate balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.**

- **Use the catheter prior to the "Use Before" date specified on the package.**

VI. **Precautions**

- Precautions are specific for the subject balloon catheter. For example, Balloon-on-a-wire catheters should include the following statement:

  "Clinical data suggest a greater incidence of catheter malfunction for this type of PTCA catheter, i.e., on-the-wire PTCA catheters, as compared to conventional over-the-wire PTCA catheters."

- Balloon on-the-wire catheters must also include a caution regarding torquing the device, specific problems that might arise and methods for dealing with these problems.

VII. **Adverse Effects**

Possible adverse effects include, but are not limited to, the following:

- **coronary artery dissection, perforation, rupture or other injury**
- **conduction disturbance**
- **acute myocardial infarction**
- **unstable angina**
- **arteriovenous fistula**
- **coronary artery spasm**
- **total occlusion of the coronary artery**
- **hemorrhage or hematoma**
- **embolism**
- **infection**
- **restenosis of the dilated artery**
- **drug reactions, allergic reaction to contrast medium**
- **hypo/hypertension**
- **death**

VIII. **Instructions for use** - Provide specific instructions for use of the subject balloon catheter.

Reference to "Working Pressure" should be eliminated from the labeling. Instead the term "Nominal Diameter Inflation Pressure" should be used. A compliance chart of balloon diameter versus inflation pressure must be included.

XI. **References** *

- Cite appropriate, current references.

- **Include date of modified labeling**

* NOTE: In the future, a table using ACC data outlining success and complication rates for different lesion types (e.g., heavily calcified lesions, diffuse lesions, chronic total obstructions, etc.) will be included in this section. FDA is currently in the process of determining the appropriate content of this table and will advise sponsors when this process is complete.